

TEMPLATE A

(Total effective dose less than or equal to 0.3 rem)

This research study involves exposure to radiation from *(insert type of procedure or procedures)*. Please note that this radiation exposure is **not** necessary for your medical care and is for research purposes only. The total amount of radiation you will receive in this study is from *(insert maximum number)* injections *(scans or repetitions)* of *(insert quantity of radioactive material, in units of millicuries; or type of x-ray procedure)*. The NIH Radiation Safety Committee has reviewed the use of radiation in this research study and has approved this use as involving minimal risk and necessary to obtain the research information desired.

Using the standard way of describing radiation dose, from participating in this study, you will receive a total of (XX) rem to your *(insert highest-dosed organ)*. All other parts of your body will receive smaller amounts of radiation. Although each organ will receive a different dose, the amount of radiation exposure you will receive from this study is equal to a uniform whole-body exposure of less than *(insert total effective dose value)*. This calculated value is known as the “effective dose” and is used to relate the dose received by each organ to a single value. The amount of radiation you will receive in this study is below the dose guideline established by the NIH Radiation Safety Committee for research subjects. This guideline is an effective dose of 5 rem (or 5,000 mrem) received per year.

For comparison, the average person in the United States receives a radiation exposure of 0.3 rem (or 300 mrem) per year from natural background sources, such as from the sun, outer space, and from radioactive materials that are found naturally in the earth’s air and soil. The dose that you will receive from participation in this research study is about the same amount you would normally receive in *(insert number)* months from these natural sources. If you would like more information about radiation and examples of exposure levels from other sources, please ask the investigator for a copy of the pamphlet called, *An Introduction to Radiation for NIH Research Subjects*.

One possible effect that could occur at these doses is a slight increase in the risk of cancer. Please be aware that the natural chance of a person getting a fatal cancer during his/her lifetime is about 1 out of 4 (or 25 percent). The increase in the chance of getting a fatal cancer, as a result of the radiation exposure received from this research study, is less than 1 in 25,000 (or much less than 1/100th of a percent). Therefore, the total risk of fatal cancer may be estimated to increase from 25 percent to 25.01 percent. This additional risk is too small to be measured and is generally regarded as insignificant.

Please tell your doctor if you have taken part in other research studies or received any medical care at the NIH or other places or hospitals that used radiation. This way we can make sure that you will not receive too much radiation. Consider x-rays taken in radiology departments, cardiac catheterization, and fluoroscopy as well as nuclear medicine scans in which radioactive materials were injected into your body.

If you are pregnant or breast feeding, you may not be able to participate in this research study. It is best to avoid radiation exposure to unborn or nursing children since they are more sensitive to radiation than adults.